

TABLE ONE Michaels M and Seifer SD. *Involving Communities as Partners in Cancer Clinical Trials, August 2007*

CURRENT MANNER OF IMPLEMENTATION	COMPONENTS of THERAPEUTIC CANCER CLINICAL RESEARCH	A NEW VISION for IMPLEMENTATION, USING CBPR PRINCIPLES
<p>Most are standing disease committees (i.e., breast, colon) modality committees (i.e. surgery, pharmacology) patient oriented (i.e., behavioral, cancer control, outcomes) or working groups. Most groups have appointed membership, with a committee chair. Executive committee approves all trials. Selected advocates (mostly survivors) may be appointed to serve on certain committees.</p>	<p>Committee established with key members, usually within cooperative group/national level</p>	<p>All committees that are responsible for developing and approving new trials are required to have community representation.¹ Community representatives are compensated adequately for their time and expertise. Community representatives have full vote on decision making bodies, and are not just advisors.</p>
<p>Issues are identified based on clinical data and funding priorities.</p>	<p>Research question(s) identified/concept developed, usually within cooperative group/at national level</p>	<p>Research team seeks full participation of the community in identifying clinical issues of greatest importance, ensuring that the study's rationale/specific research questions are able to answer issues of clinical and therapeutic importance, including but not limited to feasibility from a prospective participant's view point. Community representatives have full vote on decision making bodies, and are not just advisors.</p>
<p>Design is based entirely on scientific rigor; funding is only available for research expenses.</p> <ul style="list-style-type: none"> Phase III: National experts develop and vet concept and protocol; local investigators sign up for trial. Early phase: Trials are designed and implemented by research institutions. Trials are solely clinical and laboratory testing; researchers design intervention based on clinical data and earlier studies. 	<p>Trial designed (i.e., rationale, objectives, endpoints, eligibility, schema)</p>	<p>Community representatives are involved with all aspects of study design. Community representatives and community providers consider the potential impact of the study for future patients and the broader community. Researchers communicate specific study design approaches and work with community representatives to:</p> <ul style="list-style-type: none"> Consider more acceptable approaches, such as a cross-over design that could provide benefit to all randomized groups; Ensure that the trial design is not overly burdensome, has realistic eligibility criteria that meets the needs of the community, has endpoints that are meaningful to patients, carefully balances patient burden (tests, procedures) in consideration of answers to be gained;² Consider inclusion of quality of life correlative studies; Ensure that all psychometric instruments are developed with community input and tested in similar populations.
<p>Common forms used; researchers may use National Cancer Institute's "easy to read template" or seek patient advocate review.³</p>	<p>Consent form and process developed</p>	<p>Those writing must ensure readability at an 8th grade level and include community representatives' review. This review must include standard of care; clarity and understandability of research question, risks and benefits; alignment between the protocol and the informed consent.</p>
<p>Solely related to capacity to identify and consent patients, as well as manage patient data.</p>	<p>Qualifications for local research team developed</p>	<p>Whenever possible, the research team includes community members in a voluntary or staff capacity, which may include a CAB. Research team includes individuals who can relate to the participants, have similar backgrounds, understand the participants' experiences, speak their language and are respectful of community structures. Those conducting clinical research in minority communities strive to ensure that teams include people with the same cultural, racial/ethnic, and language backgrounds as prospective research participants. Individuals should have familiarity with particular community customs, patterns, and values; mere racial or ethnic concordance is not sufficient.</p>
<p>Cooperative group executive committee approves trials, and then submits to the NCI, which reviews for redundancy, scientific merit, patient safety and ethics considerations. Several newer initiatives (Intergroup, Concept Evaluation Panels, the Clinical Trials Support Unit and the Central IRB) have been designed to reduce time for review.</p>	<p>Trial submitted for approval and funding/peer review for scientific merit</p>	<p>All protocols/proposals being reviewed should demonstrate evidence of meaningful community involvement in the development process and community support for what is being proposed. Such involvement can build grant writing capacity among community leaders, so that they may pursue related research or programmatic agendas considered important and relevant to their communities. Through their participation, community groups are also encouraged to advocate for additional funding needed for trial implementation.</p>
<p>Funds for cooperative groups are competed through NCI cooperative agreement, which only funds about 60% of costs. Remaining costs are offset through agreements with pharmaceutical companies. Current per patient reimbursement is far below cost. Community participation on funding agency peer review panels is extremely rare.</p>	<p>Funding received/funds distributed</p>	<p>Sufficient funds are made available at the local level for CABs and recruitment and retention initiatives. Community members participate on peer review panels that review proposals for funding and are oriented, prepared and compensated for that role.</p>

<p>Investigators choose cooperative group trials based on their own interest and their assessment of appropriateness to the community.</p>	<p>Trial “sign up” by local investigators</p>	<p>Local team seeks full participation of the community in identifying clinical issues of greatest importance, ensuring that the study’s rationale/specific research questions are able to answer issues of clinical and therapeutic importance. Community representatives provide guidance to investigators as to appropriateness of the study design, its fit with the community, including but not limited to: eligibility criteria, patient burden and impact of disease in community. “Community consent,” as discussed in section V, is operationalized in a meaningful and respectful manner. Community representatives serve on decision making bodies, not just as advisors.</p>
<p>Before any patient can participate, all clinical trials⁴ must be reviewed and approved by an IRB. Federal regulations require that an IRB include at least five people of diverse occupations and backgrounds; at least one member must have primarily scientific interests, and another member must have primarily non-scientific interests. The IRB reviews the protocol to ensure the study is conducted fairly and participants are not likely to be harmed. The IRB also decides how often to review the trial once it has begun. An ad hoc IRB member may be used for specific types of research.</p>	<p>Institutional review board (IRB) approval and monitoring</p>	<p>IRB has 20% community (non-scientific, unaffiliated) members. All community IRB members are properly oriented, trained, mentored and compensated for their time. IRB members are trained to think beyond the form as the only way to obtain informed consent and are required to receive training in health literacy issues. Community representatives are involved with all aspects of developing a consent process that uses an easy to understand form, but also one that uses consenting approaches beyond the traditional form. IRB requires that community ombudsman with no financial tie to the study is present during informed consent.</p> <p>IRB membership is disclosed to the community; each IRB is required to hold public meetings about its work, enhancing trust between the institution and community. IRB annual reviews are provided to each trial participant in easy to understand language. An ad hoc IRB member for specific populations (such as non English speaking) is used as needed. Monitoring includes community ombudsman to gain appropriate early community feedback. A mechanism for assuring community consent and considering community ethical issues/impact is in place (e.g., community advisory board, community review board) and coordinates with the IRB.</p> <p>Along with IRBs, institutions are required to develop a site specific “recruitment and retention board,” which would have similar authority to an IRB, and would approve all recruitment and retention plans for individual studies. Accrual numbers are reviewed at least annually for both community representation and accrual with proportionality of disease burden and/or local population demographics.</p>
<p>Trial Implementation</p>		
<p>Research teams, as detailed above, along with institutional administrators, implement the protocols to be used in the study.</p>	<p>Data collection protocols implemented</p>	<p>Research teams as detailed above, along with institutional administrators, implement the protocols to be used in the study.</p>
<p>May be done through letters to local doctors, the research institution website, or advertisements.</p>	<p>Communication of trial availability</p>	<p>Institution in which research is being conducted is required to engage in locally appropriate educational activities with community groups regarding its research. Community members are hired to serve in roles similar to community health workers and lay outreach workers. Research institutions must collaborate with existing community infrastructure (e.g., clinics, churches, and associations), to communicate information about the trial and work to improve the health and welfare of the community.</p>
<p>Approaches to recruitment and retention are based on statistical power. This is not part of the protocol development; usually considered once a study is open for accrual. Recruitment plans are rare. Unlike peer-review funded behavioral or cancer control trials, many clinical trials generally lack direct funding for recruitment activities.</p>	<p>Recruitment and identification of potential participants</p>	<p>Recruitment plan is developed with the guidance of community representatives. Community members hired to serve in roles similar to community health workers and lay outreach workers. Research institutions must collaborate with existing community infrastructure (e.g., clinics, churches, associations) in developing and implementing recruitment plan.</p>
<p>Patients are screened through internal systems; discussion may be raised by doctor if she/he feels patient would be suitable. Assurance of patient understanding is not uniformly applied. Consent process implemented by Clinical Research Associate or Nurse; often involves reading form aloud. There is no specific training on the consent process for these staff members. Consent is often described as a task to be done (i.e. need “to consent” someone), which focuses on informed consent as a product rather than a process.</p>	<p>Screening, initial consent and accrual</p>	<p>All patients are informed about clinical trial availability at time of initial consultation with physician. Emphasis on principles of autonomy, justice, and full comprehension. Consent is done by trained staff; on-site advocates/ombudsmen are available to help participants understand the details of a proposed study. Study participants and investigators can articulate the potential direct benefits of research and the communal benefits that would result.</p>

<p>During annual review, the IRB examines a progress report on the study; IRB decides whether or not the project should continue as described in the original research plan. IRB can suspend or terminate approval if the study appears to be causing unexpected serious harm to participants. Researchers are required to keep participants up-to-date on any new information that may impact their decision to remain enrolled in the trial, but there is no requirement for ongoing communication.</p>	<p>Ongoing informed consent and communication</p>	<p>Annual progress reports are “translated” into lay language and sent to all participants. Proof of ongoing communication is required by both IRB and Data Safety Monitoring Board (DSMB). Also see above on IRB approval and monitoring.</p>
<p>Retention plans are rare. Unlike peer-review funded behavioral or cancer control trials, many clinical trials generally lack direct funding for retention activities.</p>	<p>Participant retention</p>	<p>Retention plan is integral part of recruitment plan, as discussed above. There is frequent acknowledgement and appreciation to trial participants through newsletters, cards, and events. Trial participants are given opportunity to discuss their experiences with those considering participation.</p>
<p>Made up of physicians, statisticians, and patient advocates, a majority of whom are not connected with the trial.⁵ Board reviews data periodically to determine: 1) if there are unexpected or severely toxic effects; and 2) the treatment outcome of the trial. DSMBs are required to produce summary reports that provide regular feedback to the IRBs. If participants are experiencing unexpected and severe side effects, or there is clear evidence that the risks are outweighing the benefits, then the IRB and the DSMB will recommend that the trial be stopped early.</p>	<p>Data safety monitoring board (DSMB) monitoring</p>	<p>Membership in DSMB includes community representatives and patient advocates. Annual progress reports are “translated” into lay language and sent to all participants. Proof of ongoing communication is required by both IRB and DSMB.</p>
<p>Data analyzed and interpreted by sponsor and study team.</p>	<p>Data analysis and interpretation</p>	<p>Community representatives are offered the opportunity to participate in data analysis and interpretation of findings. Training is provided to equip them with the skills to meaningfully participate and they are adequately compensated for their time.</p>
<p>Researchers report the findings from statistical analysis, publish in peer-reviewed journals, and present at professional meetings. Negative findings may not be published.</p>	<p>Dissemination of findings</p>	<p>Community members play an active role in dissemination of findings to patients as well as the greater community. All sponsors and investigators are required to distribute results through specific processes that go beyond medical journals or conferences. All trial results must be published on the web for the public and for health professionals in easily understood language. All participants receive these results as a courtesy. Journals should set standards for consumer consultation at all stages of clinical research submitted for publication. Wherever possible, consumer peer review of submitted papers should be sought. Journals should seek consumer commentaries on published papers.</p>
<p>Subsequent to reports above, the standard of care may change and new agents may be approved by the Food and Drug Administration (FDA). No systematic way to determine if all oncologists apply the new knowledge in their practices.</p>	<p>Translation of positive findings into standard care provision</p>	<p>Community partners disseminate information to their constituencies with the aim of arming patients with knowledge they need to inquire about the latest research findings and the standard of care that should be provided. Community partners assist in advocacy for policy changes needed (i.e., changes in health insurance policy, Medicaid reimbursement rates, etc).</p>